510(k): k111576

SEP 20 2011

Traditional 510(k) Summary

A) SUBMITTED BY:

NeuroTherm, Inc.
30 Upton Drive, Suite 2
Wilmington, MA 01887-1083
Registration # 1226344

CONTACT:

Sharyn Orton, PhD
MEDIcept Inc.
200 Homer Ave
Ashland, MA 01721
401-330-8264
508-231-8861 Fax

B) DEVICE NAME: NT 2000 Lesioning Generator

COMMON NAME: Generator, Lesion, Radiofrequency

DEVICE CLASS: 21 CFR 882.4400 Radiofrequency lesion generator, Class II

PRODUCT CODE: GXD

C) PREDICATES:

- NeuroTherm NT 1000 RF Lesioning Generator (K052878)
- Stryker Multi-Gen Lesioning Generator (K071482)
- Cosman G4 Radiofrequency Generator (K082051)

D) DEVICE DESCRIPTION:

The NeuroTherm NT 2000 is a desktop RF lesioning generator, which is used for the lesioning of neural tissue. The device is a second generation device that is a modification of the NeuroTherm NT 1000 (K052878) previously cleared by FDA.

The NT 2000 is a multi-lesioning, 4 channel portable generator that can provide continuous or pulsed RF output at 460 KHz, monopolar or dual electrode modes, and a Simplicity mode for large lesion creation. The device includes sensory and motor stimulation functions to fine tune electrode placement for procedures, and is also designed to connect to various lesioning probes which are inserted into patients for lesioning of neural tissue during medical procedures.

Device features include a touch screen monitor incorporating microprocessor and graphics display for user interface as well as self diagnostics, calibration checks, and recordkeeping functions.

E) INTENDED USE: The NT 2000 is intended for lesioning of neural tissue. It is to be used *only* with FDA cleared lesion/temperature probes (NeuroTherm radiofrequency probes and Smith & Nephew SPINECATH™ and ACUTHERM™ catheters). It is indicated for use in the peripheral nervous system.

F) SUBSTANTIAL EQUIVALENCE COMPARISON AND DISCUSSION

Table 1 – Intended Use/Indication for Use

	NeuroTherm NT 2000 Generator	**NeuroTherm NT 1000 Generator**	**Stryker Multi-Gen**	**Cosman G4 RF Generator**
		K052878	K071482	K082051
Product codes		GXD	GXD, GEI	GXD
Intended Use Indication for Use	Intended for use for lesioning of neural tissue. Indicated for use in the peripheral nervous system. To be used only with FDA cleared NeuroTherm RF probes. To be used only with FDA cleared the Smith & Nephew SPINECATH and ACUTHERM catheters.	Intended for use to create lesions in neural tissue. Intended for use in pain management To be used with NeuroTherm RF probes, Smith & Nephew SPINECATH, ACUTHERM catheters, Radionics DiskTrode radiofrequency probes	With Stryker electrodes is intended for coagulation of soft tissues in orthopedic, spinal and neurosurgical applications. With Smith & Nephew SPINECATH and ACUTHERM catheters, is intended for coagulation and decompression of disc material.	Indicated for use in procedures to create RF lesions for treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures. Used with Cosman RF probes.

Table 2 Predicate comparisons

	NeuroTherm NT 2000 Generator	**NeuroTherm NT 1000 Generator**	**Stryker Multi-Gen**	**Cosman G4 RF Generator**
Power output	Max power output 50W into 100 Ω.	Max power output 30W into 200 Ω.	50W max into 100 Ω	50W
Continuous RF Frequency	460 kHz	480 kHz	1 MHz	480 kHz
Stimulation – sensory and motor	Yes	Yes	Yes	Yes
Energy delivery during multi channel RF treatment	Continuous independent simultaneous energy delivery	Sequential non simultaneous energy delivery	Sequential non simultaneous energy delivery	Continuous independent simultaneous energy delivery
RF energy delivery modes:				
Continuous thermal	Yes	Yes	Yes	Yes
Pulsed RF	Yes	Yes	Yes	Yes
RF energy delivery channel types				
Monopolar	4	3	4	4
Bipolar*	Yes aka "dual"	Yes aka "dual"	Yes aka "parallel bipolar"	Yes aka "bipolar pair"

* current between two monopolar electrodes

	NeuroTherm NT 2000 Generator	**NeuroTherm NT 1000 Generator**	**Stryker Multi-Gen**	**Cosman G4 RF Generator**
Printer	Yes	Yes	No	Yes
Wireless mouse	No	No	No	Yes
Touch screen	Full operation	Set up only	Full operation	Full operation
Excess power safety feature	Yes	Yes	Yes	Yes
Excess temperature safety feature	Yes	Yes	Yes	Yes
Foot print	370 x 320 x 430 mm (W x H x D)	400 x 300 x 415 mm (W x H x D)	317 x 203 x 381 mm (W x H x D)	362 x 241 x 300 mm (W x H x D)
Weight	11.4 kg	12.5 kg	8.2 kg	10 kg

Touch screen dimensions	14" diagonal	12" diagonal	5.5 in x 8 in. 160^0 viewing angle	12 in
Electrical safety/EMC	IEC 60601compliant	IEC 60601compliant	IEC 60601compliant	IEC 60601compliant

CONCLUSION

The NT 2000 is similar to or the same as the predicate devices as follows:

- Technology
- Intended use/Indication for Use
- Technical specifications, or ranges of technical specifications
- Functional modes compared to other 4-channel devices

Where the NT 2000 differs from the NT 1000, it is similar to or the same as the other predicate devices.

Any differences between the NT 2000 and the predicate 4-channel devices do not raise new issues of safety or effectiveness. Therefore, the NT 2000 is substantially equivalent to the predicate devices based upon the Intended Use, technology, functional modes, hardware and software components, and performance.

G) PERFORMANCE TESTING

There are no applicable performance Consensus Standards or Guidance documents associated with this device.

Bench – Bench testing supports that the NT 2000 performs as expected.
Software – Software testing supports that the NT 2000 performs as expected.

H) OTHER - Compliance with Standards

This device is IEC 60601compliant as appropriate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neurotherm, Inc.
c/o Mr. F. David Rothkopf
President
MEDIcept, Inc.
200 Homer Avenue
Ashland, MA 01721

SEP 20 2011

Re: K111576
Trade/Device Name: NT 2000
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator
Regulatory Class: II
Product Code: GXD
Dated: August 23, 2011
Received: August 24, 2011

Dear Mr. Rothkopf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K111576

Device Name: NT 2000

Indication for Use: The NT 2000 is intended for use for lesioning of neural tissue. The NT 2000 is indicated for use in the peripheral nervous system.

The NT 2000 is to be used *only* with FDA cleared NeuroTherm RF probes and Smith & Nephew SPINECATH and ACUTHERM catheters.

Prescription Use X 21CFR 801, Subpart D **OR** Over-the-Counter Use _ 21CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K111576